

Creatinine Standardization Program

Recommendations for Software Vendors*

The National Kidney Disease Education Program (NKDEP), in collaboration with the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the European Communities Confederation of Clinical Chemistry (EC4), has launched the Creatinine Standardization Program to reduce inter-laboratory variation in creatinine assay calibration and provide more accurate estimates of glomerular filtration rate (GFR). The effort is part of a larger NKDEP initiative to help healthcare providers better identify and treat chronic kidney disease in order to prevent or delay kidney failure and improve patient outcomes.

Software vendors are crucial partners in the successful implementation of this program. The following steps are necessary to ensure a smooth transition from traditional calibration of routine creatinine methods to calibration that is traceable to an isotope dilution mass spectrometry (IDMS) reference method:

- 1) Software provided for laboratory information should change the equation used to estimate GFR to the Modification of Diet in Renal Disease (MDRD) Study equation. Software should provide an option to use either the original MDRD Study equation or the IDMS-traceable MDRD Study equation so that laboratories can use the equation appropriate for the calibration of their creatinine method.
- 2) Because there are legacy recommendations for drug dose adjustments based on the Cockcroft-Gault equation, an option should be provided to adjust the creatinine value used in that equation based on the relationship between an IDMS-traceable creatinine value and the legacy creatinine method used with the Cockcroft-Gault equation. The creatinine method manufacturer will provide the adjustment parameters; however, the software should be flexible to accept constant and proportional parameters.

More information about the Creatinine Standardization Program and recommendations for other groups, including clinical laboratories and pharmacists and authorized drug prescribers, are available at www.nkdep.nih.gov/labprofessionals.

Contact Information

For assistance, please contact us at csp@info.niddk.nih.gov or call 301-435-8116.

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